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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09-736,728	03-16/2001	Mahendra S. Rao	U1-0030	7449

7590

10/24/2002

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 10/24/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/736,728

Applicant(s)

Rao et al

Examiner

Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 29, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above, claim(s) 1-12 and 20-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-19 and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 6) ☐ Other: _____

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DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group III (claims 13-19 & 49) in Paper No. 8 is acknowledged. The traversal is on the ground(s) that a "search for art relating to glial restricted precursors cells would clearly also reveal art relating to methods for their isolation, methods for differentiation into glial cells and methods of use of these cells". This is not found persuasive because each group is directed toward different products, or toward different methods using different products with different stated goals, in which these separate groups have further acquired a separate status in the art as shown by their different classification. Therefore, the lack of coextensiveness of the search and examination for each distinct group would constitute an undue burden on the examiner to search and consider all the separable groups, for the reasons previously made of record. The requirement is still deemed proper and is therefore made FINAL.

Claims 1-12 & 20-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Claim Rejections - 35 U.S.C. § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 13, 16-19 & 49 are rejected under 35 U.S.C. 102(e) as being anticipated by Johe et al. (U.S. Patent 5753506).

Johe et al. teach a method of obtaining and propagating CNS glial precursor cells from mammalian/E12-E18 embryonic rats and 45-114 day old fetal humans in serum free/minimal essential salts medium plus the factor, bFGF, as evidenced by "exhibiting glial characteristics and unable to differentiate into neurons" (e.g., cols.13-14; as it relates to claim 49 & 17). Differentiation of these cells into a population of process bearing (inherently A2B5+GFAP+) astrocytes is taught by Johe when these glial precursor cells are treated with the factor, CNTF (col. 17, lines 31-37; Fig. 3 G-H; Tables IV-V; as it relates to claims 13 & 16-17). When these cells are alternatively treated with PDGF and thyroid hormone (T3), differentiation to oligodendrocytes result (e.g., col. 17, line 38-53; Fig. 3E-F & I-J; Tables IV-V; as it relates to claims 18-19 & 49).

3. Claims 13-19 & 49 are rejected under 35 U.S.C. 102(e) as being anticipated by Jat et al. (U.S. Patent 5688692).

Jat et al. teach a method of obtaining and propagating a population of mammalian/E18 embryonic rat CNS glial precursor cells that are also differentiated into non-process bearing

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A2B5-GFAP+ astrocytes and A2B5+ oligodendrocytes in the presence of the factors, PDGF, bFGF (i.e., col. 25; as it relates to claims 13-14, 18-19 & 49), as well as in the presence of the factor, purified cortical astrocyte conditioned medium, which contains 10% fetal calf serum (i.e., col. 23, lines 47-54; as it relates to claims 14 & 15) that inherently also contains thyroid hormone (T3); absent evidence to the contrary (e.g., col. 25; as it relates to claims 18-19). In that Jat et al further disclose a method of differentiation of glial restricted precursors in the presence of bFGF and CNTF, process bearing A2B5+GFAP+ astrocytes are also reasonably produced in their method (i.e., col. 25; as it relates to claims 16-17), as claimed.

4. Claims 13-18 & 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Gard et al.

Gard et al. teach a method of obtaining and propagating rat cerebral progenitor cells (e.g., G_{D3+}-O4- and GFAP+ CNS glial progenitor cells) in BDM minimal salt medium containing 0.5% fetal calf serum (FBS) which inherently contains PDGF and FGF; absent evidence to the contrary (i.e., pgs. 597-598; as it relates to claim 49). Gard teach the method of switching these cells upon culturing under differentiating conditions (i.e., in the presence of CNTF) to produce a stellate astrocytic/glial phenotype (i.e., inherently process bearing A2B5+GFAP+; pgs. 598, 2nd col.- pg. 600; Fig. 1 & 4 & Table 4; as it relates to claims 13 & 16-18). Differentiation of O4+ glial progenitor/precursor cells into oligodendrocytes is also disclosed by Gard using CNTF (e.g., pg. 600, col. 2- pg. 601; as it relates to claim 18). Differentiation of O4+ glial precursor cells into non-process bearing A2B5-GFAP+

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astrocytes in the presence of fetal calf serum (FBS) is further disclosed on pages 601-602 (i.e., as it relates to claims 13-15).

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.
October 21, 2002



GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800